K012154
Page 1 of 4

SEP 1 9 2001

Aurora Imaging Technology, Inc.
39 High Street • North Andover, MA 01845
TFP: 877.975.7530 • P: 978.975.7530
F: 975.978.9930

1.0 SUBMITTER INFORMATION:

1.1 Submitter: Aurora Imaging Technology, Inc.
39 High Street
North Andover, MA 01845
Medical Establishment Registration No.: 1225267
TFP: **877**.975.7530x4313
P: **978**.975.7530x4313
F: **978**.975.9930
C: **412**.596.2578
E: jrogers@auroramri.com

1.2 Contact: James Jochen Rogers

1.3 Date: September 5, 2001

2.0 DEVICE NAME:

2.1 Classification Panel: Radiology

2.2 Classification Number: 892.1000 Magnetic Resonance Diagnostic Device

2.3 Product Nomenclature: System, Nuclear Magnetic Resonance Imaging

2.4 Product Code(s): 90LNH

2.5 Trade/Proprietary Name: AURORA

2.6 PREDICATE DEVICE(s):

AURORA K003561

3.0 DEVICE DESCRIPTION:

3.1 FUNCTION:

The AURORA Magnetic Resonance Diagnostic Device is being enhanced by a "forklift upgrade" to increase the clinical utility of the AURORA in the stationary configuration. With the "forklift upgrade," the AURORA is available in a stand-alone configuration, and as an upgrade path to existing AURORA installations.

The "forklift upgrade" enhancement is an alternate main MRI magnet, operating at a nominal field strength of 0.5T, and improved RF-chain and gradient-chain subsystems. No changes in software or pulse sequences were necessary to support full functionality of these "forklift upgrade" enhancements.

3.2 SCIENTIFIC CONCEPTS:

Magnetic Resonance (MR) is based on the fact that certain atomic nuclei have electromagnetic properties which cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nucleus used in current imaging experiments in magnetic resonance. When placed in a magnetic field, there is a slight net orientation or alignment of these atomic nuclei with the magnetic field. The introduction of a short burst of radiofrequency (RF) excitation of wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a reorientation of the proton's magnetization vector. When the RF excitation is removed, the proton relaxes and returns to its original orientation. The rate of relaxation is exponential, and varies with the character of the proton and its adjacent molecular environment. This reorientation process is characterized by two exponential relaxation times called T1 and T2 which can be measured.

These relaxation events are accompanied by an RF emission or echo which can be measured and used to develop a representation of these emissions on a three dimensional matrix. Spatial localization is encoded into the echo by varying the RF excitation and by appropriately applying magnetic field gradients in x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of NMR characteristics of the nuclei under consideration can be constructed by using image processing techniques similar to those used in CT.

For magnetic fields up to 1.5T, the RF frequencies commonly used range up to 65MHz. The RF fields have pulse powers from several watts to greater than 10 kilowatts, and repeat at rates from once every few seconds to greater than fifty per second. The time-varying magnetic gradient fields have a typical duration of sub-millisecond to several milliseconds.

3.3 PHYSICAL AND PERFORMANCE CHARACTERISTICS:

MR is currently of great interest because it is capable of producing high quality anatomical images without the associated risks of ionizing radiation. In addition, the biological properties that contribute to MR image contrast are different from those responsible for x-ray image contrast. In x-ray imaging, differences in x-ray attenuation, largely based on differences in electro density are responsible for the contrast observed in x-ray images. In MR imaging, differences in proton density, blood flow, and relaxation times T1 and T2 all may contribute to image contrast. In addition, by varying the duration and spacing of the RF pulses, images may be produced in which the contrast is primarily dependent on T1 relaxation, T2 relaxation, proton density, or a combination of all three.

3.4 DEVICE TECHNOLOGICAL CHARACTERISTICS:

Identical to the Predicate Device.

4.0 DEVICE INTENDED USE:

The AURORA MR system is an imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, and oblique cross-sectional images that display the internal structure of the extremities (breast tissue, axilla, and chest wall local to the breast). The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

The AURORA is a dedicated breast MRI system intended to be used as an adjunct to conventional breast screening methods.

- Anatomical Region: Breast tissue, axilla, and chest wall local to the breast
- Nucleus excited: Proton
- Diagnostic uses: 2D,3D T1- / T2-weighted imaging
  T1, T2, proton density measurements
  image processing
- Imaging capabilities: 2D Spin Echo (SE)
  2D/3D Gradient Echo (GRE)
  Fat Suppression
- Imaging processing: Image Subtraction
  Image Filtering

5.0 GENERAL SAFETY AND EFFECTIVENESS CONCERNS:

Operation of the AURORA MRI System is substantially equivalent to standard operation of the predicate device. Operation of all MRI Systems is contraindicated for the following classes of patients:

- Patients with pacemakers or other electrically- or magnetically activated implants.
- Patients with intracranial aneurysm clips, unless the physician is certain that the clip is not magnetically active.

Operation of all MRI Systems for the following classes of patients requires particular caution, however, these classes of patients are not contraindicated:

- Patients with implanted surgical clips or other ferromagnetic material
- Patients engaged in occupations or activities which may cause accidental lodging of ferromagnetic materials (especially in the eyes), or who may have embedded metal fragments from military activities
- Neonates and infants (for whom data establishing safety are lacking)
- Patients with permanent tattoo eye-liner, or with facial make-up (severe eye irritation has been reported)
- Patients with compromised thermoregulatory systems
- Patients with metallic implants, because they may cause artifacts in the diagnostic images due to magnetic field distortion
- Patients who are, or are suspected to be, pregnant. The safety of magnetic resonance imaging has not been completely established for embryos and fetuses.

The reader is referred to internationally-accepted safety standard, IEN/EC 60601-2-33, (first edition), Medical Electrical Equipment, Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis for more detailed MRI safety information.

6.0 SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

Laboratory and clinical testing to internationally-accepted standards were performed to support this claim of substantial equivalence. It is the manufacturer's contention that the AURORA MR System does not include any new indications for use, and that use of the device does not pose any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Mr. James Jochen Rogers
Director, Regulatory Affairs
& Quality Assurance
Aurora Imaging Technology, Inc.
39 High Street
NORTH ANDOVER MA 01845

Re: K012154
Trade/Device Name: Aurora (MRI)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Imaging System
Regulatory Class: II
Product Code: 90 LNH
Dated: June 29, 2001
Received: July 11, 2001

Dear Mr. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

510(k) Number (if known): K012154

Device Name: AURORA

Indications for Use:

The AURORA MR system is an imaging device, and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The MR system produces transverse, coronal, sagittal, and oblique cross-sectional images that display the internal structure of the extremities (breast tissue, axilla, and chest wall local to the breast). The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

The AURORA is a dedicated breast MRI system intended to be used as an adjunct to conventional breast screening methods.

- Anatomical Region: Breast tissue, axilla, and chest wall local to the breast
- Nucleus excited: Proton
- Diagnostic uses: 2D,3D T1- / T2-weighted imaging
  T1, T2, proton density measurements
  image processing
- Imaging capabilities: 2D Spin Echo (SE)
  2D/3D Gradient Echo (GRE)
  Fat Suppression
- Imaging processing: Image Subtraction
  Image Filtering

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801-109

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012154

(Optional Format 1-2-96)